

Notice of Allowability

Application No.

10/780,601

Examiner

Vanessa L. Ford

Applicant(s)

HSU ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 19 April 2005.
2. ☒ The allowed claim(s) is/are 1-4, 6 and 8-11.
3. ☒ The drawings filed on 19 February 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other Interview Summary.

Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claims 1-2, 8-9 and 10-11 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 3-4, 6 and 8-11, directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, mailed August 25, 2004 now subject to being rejoined. Claims 3-4, 6 and 8-11 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

2. Authorization for this examiner's amendment was given in a telephone interview with Sarah Kagan on July 8, 2005. Authorization was also given to amend claims 2-4, 6 and 10-11 and cancel claims 5, 7 and 12.

3. Amend the application as follows:

In the claims:

1. (previously presented) An isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020, deposited at the China Center for Type Culture Collection under CCTCC No.: CCTCC M 203098.
2. (currently amended) A composition comprising a suspension of the isolated microorganism strain according to ~~Claim 4~~ claim 1.
3. (currently amended) A method for treating obesity or ~~a complication thereof~~ hypercholesterolemia in a subject comprising administering to said subject with a composition comprising the isolated microorganism according to ~~Claim 4~~ claim 1.
4. (currently amended) The method according to ~~Claim 3~~ claim 3, wherein the composition further comprises *Auricularia polytricha*.
5. (cancelled)

6. (currently amended) A method for treating obesity and ~~a complication thereof~~ hypercholesterolemia in a subject comprising administering to said subject with a composition comprising the ~~strain~~ isolated microorganism according to ~~Claim 4~~ claim 1 and *Auricularia polytricha*.

7. (cancelled).

8. (previously presented) A composition according to claim 2, which is used for treating obesity or ~~a complication thereof~~, hypercholesterolemia wherein the *Lactobacillus rhamnosus* GM-020 is gram-positive.

9. (previously presented) The composition according to ~~Claim 8~~ claim 8 further comprising *Auricularia polytricha*.

10. (currently amended) The composition according to ~~Claim 8~~ claim 8, comprising a dosage of the *Lactobacillus rhamnosus* GM-020 of 10^9 CFU/ml and ~~wherein the complications is selected from the group consisting of~~ hypercholesterolemia, atherosclerosis, and coronary heart disease.

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11. (currently amended) A composition for treating obesity and a ~~complication thereof~~ hypercholesterolemia in a subject comprising the isolated microorganism according to ~~Claim 4~~ claim 1 and *Auricularia polytricha*.

12. (cancelled).

ALLOWANCE

1. This Office Action is responsive to Applicant's remarks filed April 19, 2005. All rejections of record are withdrawn in view of Applicant's amendment and remarks. Claims 1-2, 8-9 and 10-11 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 3-4, 6 and 8-11, directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, mailed August 25, 2004 now subject to being rejoined. Claims 3-4, 6 and 8-11 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on August 25, 2004 is hereby withdrawn. Claims 1-4, 6 and 8-11 are allowed.

2. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests an isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020 or a composition comprising *Lactobacillus rhamnosus* GM-020. The prior art cited neither teaches nor suggests a method of treating obesity or hypercholesterolemia comprising administering to a subject a composition comprising an isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020 nor does the prior art teach a method of treating obesity and hypercholesterolemia comprising administering to

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a subject a composition comprising an isolated microorganism of the strain

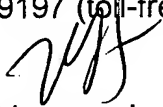
Lactobacillus rhamnosus GM-020 and *Auricularia polytricha*.

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
July 12, 2005


MARK NAVARRO
PRIMARY EXAMINER

CLEAN COPY OF CLAIMS

1. An isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020, deposited at the China Center for Type Culture Collection under CCTCC No.: CCTCC M 203098.
2. A composition comprising a suspension of the isolated microorganism strain according to claim 1.
3. A composition according to claim 2, which is used for treating obesity or hypercholesterolemia wherein the *Lactobacillus rhamnosus* GM-020 is gram-positive.
4. The composition according to claim 3 further comprising *Auricularia polytricha*.
5. The composition according to claim 3, comprising a dosage of the *Lactobacillus rhamnosus* GM-020 of 10^9 CFU/ml.

6. A composition for treating obesity and hypercholesterolemia in a subject comprising the isolated microorganism according to claim 1 and *Auricularia polytricha*.

7. A method for treating obesity or hypercholesterolemia in a subject comprising administering to said subject a composition comprising the isolated microorganism according to claim 1.

8. The method according to claim 7, wherein the composition further comprises *Auricularia polytricha*.

9. A method for treating obesity and hypercholesterolemia in a subject comprising administering to said subject a composition comprising the isolated microorganism according to claim 1 and *Auricularia polytricha*.